FINDING OF NO SIGNIFICANT IMPACT

for

Xanthan Gum

FAP 2174
Kelco, Division of Merck & Co., Inc.

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Kelco, Division of Merck & Co., Inc., has requested approval for the use of food additive Xanthan Gum in animal feed. Xanthan gum will be used as a stabilizer and thickener in liquid feed supplements for ruminant animals at a maximum use level of 0.25% and under the trade name of Kelflo®. Xanthan gum will also be used as a stabilizer, thickener, or emulsifier under the trade name of Keltrol®F in calf milk replacers at a maximum use level of 0.1% as fed.

Xanthan gum is a polysaccharide gum produced as the fermentation product of the bacterium Xanthomonas campestris. The polysaccharide is a polymer containing the naturally occurring sugars: D - glucose, D - mannose, and D - glucuronic acid in the approximate molecular proportions of 2.8:3:2. Xanthan gum is a natural product that can be found most commonly in cabbage plants. The product is not fully metabolized in its use and is biodegradable in the environment to nontoxic components. On the basis of the available information, the product is not expected to cause adverse impacts on the environment. Therefore, the action qualifies for conditional exemption under codified 21 CFR 25.1(f)(1)(iv) from the requirement to prepare an environmental impact analysis report.

Kelco, Division of Merck & Co., Inc. has submitted environmental information (attached) that adequately addresses the potential environmental impacts of the manufacturing process, as required under 21 CFR 25.1(g).

9/6/84
Date

Preparer, HFV-310

9-7-84
Date

Primary Action Officer, HFV-221

9-6-84
Date

Chief, Environmental Impact Staff, HFV-310